

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

I. Amendments to the specification

The specification is amended to correct a clerical error, *e.g.*, to clarify that isohumulones are obtained from isomerized hop extract, not hop extract directly. Exemplary support for the correction is found on page 20, lines 20-22 and 26-29, where it is plainly taught that isohumulones are obtained from isomerized hop extract. Accordingly, entry of the amendment is respectfully requested.

II. Status of the claims

Claims 1-11 and 18-23 were previously canceled without disclaimer or prejudice thereof.

Claims 13-16 and 24-36 were previously withdrawn pursuant to a Restriction Requirement.

Claim 12 is currently amended to recite specific embodiments. Parallel amendments are made to the withdrawn claims.

Claims 38 and 39 are added to recite specific embodiments, *e.g.*, methods comprising administering compositions consisting essentially of isohumulones and/or an isomerized hop extract. As provided in MPEP 2111.03, “the transitional phrase ‘consisting essentially of’ limits the scope of a claim to the specified materials or steps ‘and those that do not materially affect the basic and novel characteristic(s)’ of the claimed invention.”

These amendments do not add any new matter.

After amending the claims as set forth above, claims 12-17 and 24-39 will be pending, with claims 12, 17 and 37-39 directed to elected subject matter and presented for reconsideration.

III. Claim rejection – 35 U.S.C. § 103

Claims 12, 17 and 37 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over JP 1737741/1992 (JP ‘741) in view of U.S. Patent No. 7,279,185 (the ‘185 Patent). The Office Action alleges that JP ‘741 teaches that “a hop extract is used to treat hypertension,” but recognizes that JP ‘741 does not teach “that the hops extract is specifically a isohumulone.” (Office Action at page 3). The Office Action alleges that the ‘185 Patent cures this deficiency by teaching that “isohumulones are compounds isolated from hops.” (Id.). With this reading of the disclosures, the Office Action concludes that “it would have been in the purview of the skilled artisan to use isohumulones in the process of JP ‘741 with the expectation of success since Babish [the ‘185 Patent] establishes that isohumulones are well known to be hop extracts and since Babish yields such beneficial results from using such isohumulones.” (Office Action at pages 3-4). Applicants respectfully traverse this ground for rejection for at least the reasons provided below.

A. The Cited References Do Not Suggest the Claimed Methods

As reflected in independent claim 12, the claimed subject matter under examination relates to methods of lowering blood pressure by administering to a mammal suffering from hypertension isohumulones and/or an isomerized hop extract. Such methods are not taught or suggested by the cited references.

As a preliminary matter, Applicants note that isohumulones are compounds that can be obtained by isomerizing hop extracts or by boiling humulones to convert them to isohumulones. *See e.g.*, specification at page 20, lines 15-17, 20-23 and 26-29. Thus, those skilled in the art would not understand a “hop extract” *per se* to include isohumulones, and commercially available “hop extract” certainly does not necessarily include isohumulones. Additionally, Applicants note that humulones belong to the alpha acid group, while isohumulones belong to the iso-alpha acid group.

The cited references, whether read alone or in combination, fail to teach or suggest that isohumulones or isomerized hop extract can be used to treat hypertension. Neither reference even mentions isomerized hop extract, and there is no reason to expect that the

commercial hop extract discussed in JP ‘741 includes isohumulones, as claimed. Moreover, neither reference indicates that isohumulones or isomerized hop extract could or should be used to lower blood pressure.

JP ‘741 teaches that a *combination of multiple compounds* (a valerian extract, a maypop extract, a choto extract, a hop extract and a ginseng extract) is useful for the prevention and treatment of hypertension. Contrary to the Office Action assertion, JP ‘741 does not teach or even suggest that a hop extract alone would be useful for the treatment of hypertension, and certainly does not teach or suggest that an isomerized hop extract or isohumulones would be useful for the treatment of hypertension. Indeed, JP ‘741 fails to even mention isomerized hop extract or isohumulones. As explained above, there is no reason to expect that the “hop extract” of JP ‘741 even includes isohumulones, since there is no indication that, for example, the hop extract has been isomerized to obtain isohumulones.

JP ‘741 states that “[a] valerian extract and a hop extract have an effect of relieving excitement and tension of nerves (sedative effect).” (JP ‘741 at page 4.) This is not the same as, and can not be construed to mean, “lowering blood pressure,” as recited in the claims under examination. JP ‘741 continues, stating that “a maypop extract and a Choto extract have an effect of normalizing a neurological function (neurological function activating effect), and a ginseng extract has an effect of relieving stress (anti-stress effect).” (Id.) Thus, JP ‘741 teaches that it is only the *combination* of these *five extracts* that is useful for the prevention or treatment of hypertension. No blood pressure lowering activity is attributed to the hop extract, let alone to isohumulones or an isomerized hop extract, as claimed.

The ‘185 Patent fails to remedy the deficiencies of JP ‘741. While the ‘185 Patent teaches that alpha-acids can be “isolated from hops plant products,” and include humulones and isohumulones (‘185 Patent at col. 5, lines 13-15), the ‘185 Patent does not teach or suggest that isohumulones can lower blood pressure, and does not even mention isomerized hop extract. Moreover, as noted above, the ‘185 Patent’s classification of isohumulones as an alpha-acid is inaccurate, as is the implication that isohumulones can be isolated from hops plant products directly.

As discussed previously, the ‘185 Patent teaches the use of “alpha-acids,” including isohumulones, for treating inflammation, and as COX-2 inhibitors. These activities are distinct from, and cannot be construed as, “lowering blood pressure,” as recited in the claims under examination.

There is no credible scientific reason for a skilled artisan to identify an agent said to be useful to treat *inflammation* (e.g., isohumulones) as an agent that may have blood pressure lowering activity. Moreover, as explained above, there is no evidence that the multi-component composition of JP ‘741 even contained isohumulones, as claimed. Thus, combining the teachings of the ‘185 Patent and JP ‘741 in no way suggests the present invention.

Applicants note that claim 37 is separately patentable over the cited references, as this claim is directed to the specific embodiment where isomerized hop extract is administered. As discussed above, isomerized hop extract is not discussed in either cited reference.

Claims 38 and 39 also are separately patentable over the cited references, as these claims are directed to specific embodiments where a composition “consisting essentially of” isohumulones and/or isomerized hop extract is administered. Such compositions would not include other plant extracts or hop extract components that are present in the compositions of JP ‘741.

B. There is No Motivation to Combine the Cited References

The skilled person would have no rational reason to combine the teachings of the ‘185 Patent and JP ‘741 by, for example, replacing the hop extract of JP ‘741 with isohumulones to make a composition useful for lowering blood pressure. As discussed above, there is no information in the cited references that would support any reasonable expectation that isohumulones would have any effect on blood pressure. Moreover, the two references relate to very different physical conditions (inflammation versus hypertension) and two very different treatment compositions (isohumulones versus a combination of five different extracts). The fact that both documents refer to “hop extract” is insufficient reason to combine them with any reasonable expectation of success.

C. There is No Reason to Modify the References' Teachings

The skilled person would have no rational reason to modify the composition of JP '741 (a combination of five different extracts) by *eliminating all five of the extracts* and instead using isohumulones in an attempt to treat hypertension. As discussed above, JP '741 teaches that it is the *combination of five extracts* that is useful for the treatment or prevention of hypertension, and describes the activity of hop extract as "relieving excitement and tension of nerves (sedative effect)." This is not the same as "lowering blood pressure" as recited in the pending claims.

As discussed above, isohumulones can be obtained by isomerizing hop extracts or by boiling humulones to convert them to isohumulones. Thus, those skilled in the art would not understand a "hop extract," as taught in JP '741, to include isohumulones, and commercially available "hop extract" certainly does not necessarily include isohumulones. Indeed, there is no evidence that the "hop extract" of JP '741 even included isohumulones, as claimed. Thus, even if JP '741 did teach that hop extract has blood pressure lowering activity (which it does not), the cited references reveal no reason to replace the hop extract with isohumulones to achieve the same activity.

In summary, for at least the reasons stated above, the cited combination of references does not render the claimed methods obvious. Thus, reconsideration and withdrawal of the rejection is respectfully requested.

IV. Conclusion

The present application is now in condition for allowance. Favorable reconsideration of the application is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the

credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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